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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,890

02/23/2006

Zvika Gilad

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EXAMINER

CANDLER, SAMUEL M

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

07/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,890	Applicant(s) GILAD ET AL.	
	Examiner SAMUEL CANDLER	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-26 and 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/27/2005, 8/3/2006, 8/22/2006, 10/22/2007, 6/22/2009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species A (Claims 1-13, 16-26 and 29-38) in the reply filed on 5/15/2009 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed 8/3/2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because 60/801,385 is a later-filed provisional application and no copy of foreign document JP 09237441 A has been provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

3. The information disclosure statement filed 8/22/2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because U.S. PGPub 2001/00135902 (Cite No. H) is an improper U.S. PGPub number listing. Additionally, no translations have been provided for foreign patent documents JP 57-54833 (Cite No. V) and JP 4109927 (Cite No. AE), and no copy of foreign patent documents have been provided for JP 57-54833 (Cite No. V), JP 2001224553 (Cite No. AC), and JP 5015515 (Cite No. AF). It has been placed in the application file, but the information referred to therein has

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not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

4. The information disclosure statement filed 10/22/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because U.S. 11/802,121 (Cite No. R) and U.S. 60/801,387 (Cite No. Z) are later-filed applications, and the copy of foreign document JP 7289504 (Cite No. V) is an incomplete copy of the reference. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 7 recites the limitation "said sensing device" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 7-9, 12-13, 16-20, 22-23, 26, 29 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka et al (JP 06-114036).

9. Re claims 1-2, 7-9, 17, 19-20, 22-23, 29 and 31-37, Kosaka et al discloses an immobilizer 1, 2 (see paragraph [0010]; Drawing 1) comprising a pointed anchor 12 (see paragraphs [0010], [0013] and [0018]-[0019]; Drawing 1) activated in response to a signal (energization of the 2nd electromagnet; see paragraph [0018]) issued by a processor (means which carries out a driving operation of said fixing means; see paragraph [0006]), and an imager 6 (see paragraph [0009]; Drawing 1).

10. Re claims 3 and 18, Kosaka et al discloses a cable 4 (see paragraph [0008]; Drawing 1) power source line and various controls signals, with instruction being sent through cable 4 to electromagnet 19 causing activation of anchor 12 (see paragraph [0014]; Drawing 3).

11. Re claims 12-13 and 26, Kosaka et al discloses a composition delivery unit 32 (see paragraph [0020]; Drawing 4) wherein said composition comprises a drug.

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12. Re claim 16, Kosaka et al discloses a power source 21 (see paragraph [0015]; Drawing 3).

13. Re claims 38, Kosaka et al discloses a transmitter 11 (see paragraph [0015]; Drawing 3).

14. Claims 1-10, 16-24 and 29-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Meron et al (U.S. PGPub 2002/0042562).

15. Re claims 1-3, 7-9, 17-20, 22-23 and 31-37, Meron et al discloses an immobilizer 10 (see paragraph [0029]; Fig. 1) comprising a pointed anchor (suture; see paragraph [0029]; not pictured) capable of being activated in response to instruction received from outside a body lumen (surgeon controlled immobilization; see paragraph [0029]) using a processing element (processor; see paragraph [0029]; not pictured) and further comprising an imager 16 (see paragraph [0029]; Figure 1).

16. Re claims 4-5, 21 and 29-30, Meron et al discloses wherein an immobilizer is capable of degrading upon exposure to in vivo conditions (see paragraph [0031]).

17. Re claim 6, Meron et al discloses wherein a surgeon receives information regarding a detected environmental condition (see paragraphs [0027] and [0037]) and is able to perform immobilization (as earlier disclosed in paragraph [0029]) in response to the detected environmental condition.

18. Re claims 10 and 24, Meron et al discloses wherein an immobilizer comprises a spring releasably holding the immobilizer (shape memory alloy or polymer; see paragraph [0035]; as defined by the Merriam-Webster Dictionary, a 'spring' is being

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interpreted as 'an elastic body or device that recovers its original shape when released after being distorted').

19. Re claim 16, Meron et al discloses a power source (power source; see paragraph [0029]; not pictured).

20. Re claim 38, Meron et al discloses a transmitter (transmitter; see paragraph [0029]; not pictured).

21. Claims 1, 10-11, 17-18, 22 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hugemann et al (U.S. Patent No. 4,425,117). Hugemann et al discloses an immobilizer 20 wherein a fuse 9 reacts to a signal from an HF transmitter to release a spring 5 which in turn sets of a mechanism to feed powder or liquid into a balloon 23 which is capable of immobilizing the system (see Abstract and col. 3 line 31 - col. 4 line 14; Figures 2 and 4) and monitoring said in vivo site with the device (see col. 1 lines 53-62).

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references disclose devices capable of immobilizing in a body lumen:

U.S. Patent No. 7,160,258

U.S. PGPub 2002/0138009

U.S. PGPub 2002/0156347

U.S. Patent No. 7,261,728

U.S. Patent No. 6,527,753

U.S. Patent No. 6,458,074

U.S. PGPub 2001/0049497

U.S. Patent No. 6,648,814

U.S. Patent No. 5,782,771

U.S. Patent No. 5,108,407

U.S. Patent No. 6,579,311

U.S. PGPub 2004/0153008

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL CANDLER whose telephone number is (571)270-3410. The examiner can normally be reached on Monday - Friday, 8 a.m. - 5 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P Leubecker/
Primary Examiner, AU 3739

/SAMUEL CANDLER/
Examiner, Art Unit 3739